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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Case CM2016MC

In the Application of :
Cinelli, et al. :
Serial No. 09/917,505 : Group Art Unit : 1713
Confirmation No. 9733 :
Filed July 27, 2001 : Examiner : R. A. Lee

For **DISPOSABLE HUMAN WASTE MANAGEMENT DEVICES
WITH IMPROVED ADHESIVE FLANGE ATTACHMENT
MEANS TO FACILITATE WATER ADHESION STABILITY
WITH LOW PAIN LEVEL REMOVAL**

DECLARATION UNDER 37 CFR §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Stephen Allen Goldman, declare as follows:

That, I received a Ph.D. degree in physical chemistry with a specialty in electron spin resonance spectroscopy from Cornell University in 1973;

That, since 1972, I have been an employee of The Procter & Gamble Company in Research and Development;

That, my present title is Principal Scientist for The Procter & Gamble Company Corporate Research Development Division;

That, I am familiar with the subject matter of the above-identified Application and with elastomeric pressure-sensitive adhesives;

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That, I am familiar with the subject matter in PCT Patent Publication No. WO 98/28014 to Cinelli, et al.;

That, I am familiar with the subject matter in PCT Patent Publication No. WO 98/28021 to Cinelli, et al.;

That, Cinelli discloses in WO 98/28014 (the '014 publication) and WO 98/28021 (the '021 publication) that topical adhesives for attachment to the skin are characterized primarily by their elastic and viscous moduli at various temperatures and frequencies of measurement. The elastic and viscous moduli are determined by the composition of the two essential components of the adhesive; namely, the polymeric components and the plasticizer.

Cinelli notes on page 12, line 31 to page 13, line 10 of the '014 publication and on page 14, line 34 to page 15, line 13 of the '021 publication that, "The compositions typically comprise from 0.5 to 20%, preferably 5% to 15%, by weight of a macromolecular polymeric substance or mixture of such substances soluble or swellable in the below-mentioned plasticizers . . . from 45-99.5% by weight, preferably 51 to 99.5% by weight, of a plasticizing substance or a mixture of plasticizing substances, which are liquid at room temperature."

Cinelli also notes on page 12, lines 25-29 of the '014 publication and on page 18, lines 28-32 of the '021 publication that, "A macromolecular or polymeric component is present in minor quantities vs. the plasticizer. It forms, in the preferred embodiments, a three dimensional network caused by physical or chemical crosslinks between the molecules. Particularly useful physical crosslinks are the ones present in systems containing Block Thermoplastic Elastomers." Physical crosslinking is exemplified in '014 in the example starting on page 22, line 19. As noted in the '014 application on page 13, line 31, "When chemical crosslinks are formed in the system, a crosslinking agent can be present preferably in quantities up to 5% by weight. Chemical crosslinking can be formed also by mutual neutralisation of polymers having different functionalities as in the reaction between acid polyacrylics and polysaccharides." As can be seen from the above, there is no teaching in either Cinelli reference of forming crosslinks between polymer molecules *during* the polymerization of these polymer molecules. In fact, it is clear from the teachings of the '014 publication and the '012 publication that the crosslinks are formed from physical and/or chemical interactions between "pre-formed"

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polymers. One of skill in the art would realize that the crosslinking agent referred to in both the '014 publication and the '012 is added to pre-formed polymers to form chemical crosslinks.

In stark contrast, the adhesives for attachment to the skin disclosed and claimed by the instant Application are characterized primarily by their ability to adhere to skin under moist and wet skin conditions and their ability to maintain adhesive peel strength even under exposure to excess water. In large contrast to the cited prior art, the adhesives of the instant Application are able to absorb moisture from the wet skin and sufficiently minimize the impact of this absorbed moisture on the intrinsic characteristics of the adhesive (e.g., the aforementioned elastic and viscous moduli) that impact the peel strength.

As disclosed in the instant Application on page 5, paragraph 66, "According to the present invention, the three-dimensional matrix, also referred to herein as a gel, comprise as an essential component, a polymer which can be physically or chemically crosslinked." Further, starting on page 6, paragraph 73, "According to the present invention, the polymer component of the adhesive can be physically or chemically crosslinked in order to form the three-dimensional matrix. . . . Chemical crosslinking refers to polymers which are linked by chemical bonds. Preferably, the polymer is chemically crosslinked by low energy radiation techniques such as thermal . . . UV . . . or microwave irradiation." In addition, when chemical crosslinks are formed in the system of the instant Application, a polyfunctional crosslinker and/or a free radical initiator may be present in the pre-mix to initiate the crosslinking upon radiation." In the examples of the instant Application, such a polyfunctional crosslinker is added to the monomer mixture *prior to* UV photopolymerization in amounts ranging from 0.05-0.13%.

It is well known in the art that crosslinks formed during polymerization result in polymer networks having properties that differ from those of polymer networks formed by crosslinking pre-formed polymers, even if the polymers are formed from the same monomers. In the instant Application, it is the stability and insensitivity of the crosslinked network to an increase in the moisture content of the adhesive that are essential to sufficiently minimize the impact of moisture absorption on the intrinsic characteristics of the adhesive that impact peel strength. In recognition of this need, all of the adhesives in the examples of the instant Application are prepared via the use of low

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energy radiation (i.e., UV irradiation) in order to form chemical crosslinks during polymerization that are stable in the presence of added moisture.

Further, Declarant sayeth not.

This declaration is made with the knowledge that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed true, and further that willful false statements and the like are punishable by fine or imprisonment, or both under 18 USC §1001 and may jeopardize the validity of the application or any patent issuing thereon.

Sept 2, 2004
Date

Stephen Allen Addelman
Declarant

18 US 1001 Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than \$10,000 or imprisoned not more than five years, or both.